UNITED STATES BANKRUPTCY COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

In re:

| | |
|---|---|
| C2R Global Manufacturing, Inc., | Case No. 18-30182-beh |
| Debtor. | Chapter 11 |

**DECISION AND ORDER CONSTRUING DISPUTED CLAIMS**

This is a patent case about disposal systems for medications, against the backdrop of a bankruptcy claim objection. The Court has reviewed the parties' claim construction briefs and heard well-wrought oral argument. In the intervening period since the hearing presentation, the parties attempted mediation with retired bankruptcy judge Susan V. Kelley, but those efforts were unsuccessful. For the reasons stated below, the Court adopts C2R's proposed claim construction in some respects, and Verde's proposed claim construction in other respects.

## PROCEDURAL BACKGROUND AND JURISDICTION

On October 29, 2018, C2R Global Manufacturing, Inc. filed a petition for relief under Chapter 11 of the Bankruptcy Code. Previously, on July 29, 2018, Verde Environmental Technologies, Inc. had filed a lawsuit against C2R in the Eastern District of Wisconsin, asserting claims for false advertising under 15 U.S.C. § 1125(a) and Wisconsin Statute § 100.18, as well as claims for infringement of two of its patents, U.S. Patent No. 8,475,837 B2 (the "'837 Patent") and U.S. Patent No. 8,535,711 B2 (the "'711 Patent").[1]

After the debtor filed its bankruptcy petition, the litigation in the district court was stayed. Verde timely filed a proof of claim for $6,821,918.00, claiming the patent and non-patent related damages asserted in its district court case. C2R objected to the proof of claim, denying liability on Verde's

[1] Specifically, Verde asserts infringement of claims 1, 8, and 9 of the '837 Patent, and claims 1, 2, 6, 7, 11, and 12 of the '711 Patent.

claims and asserting counterclaims seeking a declaratory judgment that both patents are invalid. As the first step in resolving C2R's claim objection and its counterclaims, the parties have asked the Court to construe the meaning of several terms in the patents at issue.

Because this patent dispute concerns the allowance or disallowance of claims and the determination of counterclaims of the estate, this is a core proceeding under 28 U.S.C. § 157(b)(2)(B) and (C). The Court has jurisdiction under 28 U.S.C. § 1334 and the Eastern District of Wisconsin's July 16, 1984, order of reference entered under 28 U.S.C. § 157(a). To the extent that the issues may be deemed non-core but otherwise relate to the debtor's bankruptcy case, the parties have given their implicit consent to the entry of appropriate orders and judgments by the bankruptcy judge. This decision constitutes the Court's findings of fact and conclusions of law under Federal Rule of Bankruptcy Procedure 7052.

## FACTUAL BACKGROUND

Verde is a Minnesota-based corporation that develops "research-based, scientifically proven solutions to reduce drug abuse, misuse, and negative environmental impact." *See* ECF Doc. No. 49, at 7, 40. One of Verde's products is the Deterra Drug Deactivation System ("Deterra"), which deactivates prescription drugs using activated carbon. *Id.* at 40. Verde has obtained at least two patents that it asserts cover various aspects of the Deterra system: the '837 Patent, which is titled "Abuse Potential Reduction in Abusable Substance Dosage Form," and the '711 Patent, which is titled "Medication Disposal System." *Id.* at 41.

C2R, a Wisconsin corporation, is a direct competitor of Verde and sells products for the safe disposal and deactivation of prescription drugs to hospitals, pharmacies, law enforcement agencies, and individual consumers. C2R makes several models of drug deactivation and disposal products, products which Verde accuses of infringing claims 1, 8, and 9 of the '837 Patent, and claims 1, 2, 6, 7, 11, and 12 of the '711 Patent.

The claims at issue in the '837 Patent include the following language, with the disputed terms italicized:

1. A device comprising:

   (a) an independent disposable container having an opening therein *to receive a skin-worn patch device containing a residual amount of an abusable substance therein;*

   (b) a *layer* containing an amount of an anti-abuse substance comprising an adsorption material which is activated carbon that prevents solvent extraction of said abusable substance, *said layer being disposed in said container in a manner such that a skin-worn patch device properly inserted into said container will cause said abusable substance to contact said layer containing said anti-abuse substance*; and

   (c) a *closure means for closing* said container *containing a used skin-worn patch device.*

. . .

8. The device according to claim 1, *wherein said abusable substance is an opioid.*

9. The device according to claim 8, *wherein said abusable substance is fentanyl.*

10. The device according to claim 1, wherein said closure means comprises a zip lock seal.[2]

11. The device according to claim 1, wherein said layer containing an amount of an anti-abuse substance is attached to one side of said container.

12. The device according to claim 1, wherein said closure means comprises an adhesive strip on each side of said opening of said container.

[22] Verde does not allege infringement of claims 10, 11, or 12 of the '837 Patent, and therefore the parties have not asked the Court to construe their terms, but the language of these claims is relevant to the Court's analysis of the parties' arguments regarding the meaning of the term "layer," *see infra* section C.1, and "closure," *see infra* section C.3, so the Court includes the language of those claims here.

The claims at issue in the '711 Patent include the following language, with the disputed terms italicized:

> 1. *A disposal system for reducing substance abuse or environmental contamination from unused medications, said system* comprising:
>
> (a) a disposable, *sealable* container that can be opened *to receive an amount of unused medication substance therein*;
>
> (b) an amount of an active binding agent in said container *for treating said medication on contact*, said binding agent includes an amount of activated carbon that prevents later independent extraction of said medication, *such that insertion of said medication into said container will cause said medication to contact said binding agent*; and
>
> (c) said container including a *closure for sealing* said container to thereby capture a treated medication.
>
> 2. A disposal system as in claim 1 further comprising a suspension substance to suspend said activated carbon to improve contact with said medication.
>
> . . .
>
> 6. A disposal system as in claim 1 wherein said container is impervious to organic vapors.
>
> 7. A disposal system as in claim 6 wherein said closure is *resealable*.
>
> . . .
>
> 11. A disposal system as in claim 1 wherein said closure is *resealable*.
>
> 12. A disposal system as in claim 1 further comprising media *to dissolve said unused medications that are in solid form.*

## ANALYSIS

### A. Claim Construction Principles

Determination of patent infringement and validity both require a two-step process that begins with claim construction—a legal analysis where the court interprets the meaning and scope of the claims—as the first step. *See, e.g., Kemco Sales, Inc. v. Control Papers Co., Inc.*, 208 F.3d 1352, 1359 (Fed. Cir. 2000) (infringement); *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1353 (Fed. Cir. 1999) (validity). This decision concerns only the first step, claim construction.

The parties used a "fence around the house" analogy to describe the general purpose of patent law. In short, the claims of a patent define the invention to which the patentee is granted the right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). Claim construction is largely a question of law, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1966), even though it may include some fact-finding that would be subject to clear-error review on appeal. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835 (2015).

A court construing a claim term seeks to give the words of the claim their "ordinary and customary meaning" to one of ordinary skill in the relevant art. *Phillips*, 415 F.3d at 1313. "[U]nless compelled to do otherwise, a court will give a claim term the full range of its ordinary meaning as understood by an artisan of ordinary skill." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001).

The appropriate starting point in construing a claim is the "intrinsic evidence," which includes the words of the claims themselves, the patent specification, and the patent prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Phillips*, 415 F.3d at 1315. "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms," *Phillips*, 415 F.3d at 1314, and the context in which a term is used, as well as the use of the term in other claims of the patent, can be "valuable sources of enlightenment as to the meaning of a claim term." *Id.*

In addition, the claims themselves "'must be read in view of the specification, of which they are a part.'" *Id.* (quoting *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed. Cir. 1995)). At the same time, "it is improper to read a limitation from the specification into the claims." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004). The specification is all of the text and figures laid out before the claims are identified. Specifications may define claim terms, or they may just describe the invention and one or more preferred embodiments. An embodiment is an example of how to use, or "practice" an invention. The Federal Circuit has

recognized that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Id.* (internal quotation marks omitted). For that reason, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Id.* at 906 (internal quotation marks omitted).

Beyond this intrinsic evidence, the Court also may consider extrinsic evidence. Extrinsic evidence in this context may include inventor testimony, expert testimony, documentary evidence of how the patentee and alleged infringer have used the claim terms, dictionaries, treatises, and similar sources. *Phillips*, 415 F.3d at 1317–18. Extrinsic evidence is seen as less reliable in claim construction than the text of the patent itself and its prosecution history. *Id.* at 1318; *see also Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1203 (Fed. Cir. 2002) ("The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and distinctly claim the invention."). For this reason, extrinsic evidence, while instructive and proper for the Court to consider, always should be viewed in light of the intrinsic evidence. *See, e.g., Texas Digital*, 308 F.3d at 1203 ("Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor. . . If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings."). These relative weights of actual text versus extrinsic evidence are not unlike the prescriptions of statutory construction canons. Legislators, like inventors, are deemed to mean what they said by the words they actually selected. The glosses attributed by others

– experts and commentators – can be practical and helpful but do not bind courts.

Courts try to view claim terms from the perspective of "a person skilled in the art." *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003); *see also Phillips*, 415 F.3d at 1313 ("the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention"). A person of ordinary skill in the art (a "POSA," for short) is one who would address the same problems faced by the inventor. *See, e.g., KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *see also Monroe Truck Equip., Inc. v. Universal Truck Equip., Inc.*, 120 F. Supp. 3d 884, 889 (W.D. Wis. 2015). Here, C2R and Verde propose different arts in which a person should be skilled, to solve the same problems faced by the inventors of the '837 and '711 patents. Plaintiff Verde proposes that the person of ordinary skill in the art is one with a background in chemistry or pharmaceutical sciences and experience in pharmaceutical product development and the pharmaceutical industry. C2R proposes that, at least for some of the claim terms at issue, the art of packaging is the relevant art.

Prior to taking argument on the claim construction motion, the Court took argument on Verde's motion to strike C2R's expert, Dr. Claire Koelsch Sand. Dr. Sand is a packaging expert. Verde asserted that the relevant fields of art are pharmacy and chemistry. The Court denied Verde's request to strike the opinion testimony of Dr. Sand, but agreed to afford her testimony only that weight it warranted, as her testimony relates to particular challenged claim terms. Whether Dr. Sand's testimony affected the Court's construction of a particular claim term will be noted below.

**B. Means-Plus-Function Limitations**

Construing a "means plus function" claim requires a bit more analysis, because such claims are excepted from the general rule about not reading limitations from the specification into the claims. Means-plus-function

claiming occurs when a claim term is drafted in a manner that invokes 35 U.S.C. § 112(f),[3] which states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

A claim's use of the word "means" gives rise to a presumption that the inventor used the word to invoke the statutory mandates for a means-plus-function clause. But that presumption is not conclusive. If a claim uses the word "means," but then goes on to elaborate sufficient structure within the claim itself to perform entirely the recited function, the claim is not in means-plus-function format. *Sage Prod., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427–28 (Fed. Cir. 1997). Conversely, when a claim does not employ the word "means," there is a presumption that the inventor did not intend to invoke means-plus-function treatment. That presumption, however, can be overcome if the claim term "fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (internal quotation marks omitted). "The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Id.* In short, the presumption only goes so far.

If a claim is found to be written in a means-plus-function format, then the construing court must engage in a two-step analysis. First, the court must identify the specified function of the means. Then, the court must consult the specification to define the structure, material or acts corresponding to this claimed function. *Sage Prod.,*126 F.3d at 1428.

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[3] In their briefing, both parties refer to 35 U.S.C. § 112 ¶ 6, but ¶ 6 of 35 U.S.C. § 112 was replaced with newly designated sec. 112(f) when sec. 4(c) of the Leahy–Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011), took effect on September 16, 2012. Much of the relevant caselaw still refers to ¶ 6.

## C. Terms to be Construed

The parties dispute the meaning of terms used in claims 1, 8, and 9 of the '837 Patent, and claims 1, 2, 6, 7, 11, and 12 of the '711 Patent.

For ease of discussion, the parties grouped the disputed terms into five categories, which the Court now adopts in its analysis:

1. "Layer" terms ('837 Patent claim 1)
2. "Seal" terms ('711 Patent claims 1, 7, and 11)
3. "Closure" terms ('837 Patent claim 1 and '711 Patent claim 1)
4. Preamble ('711 Patent claim 1)
5. Intended use terms ('711 Patent claims 1 and 12, '837 Patent claims 1, 8, and 9)

### 1. "Layer" terms ('837 Patent claim 1)

The parties have proposed the following constructions of the disputed claim terms:

| Claim Term | Term Location | C2R's Proposed Construction | Verde's Proposed Construction |
|---|---|---|---|
| "layer" | '837 Patent Claim 1 | "solid thickness of material" | *No further construction necessary.*<br><br>Alternatively, a "quantity of material covering a surface." |
| "layer containing an amount of anti-abuse substance" | '837 Patent Claim 1 | "solid thickness of material containing a binding agent, antagonist, or irritant" | *No further construction necessary.*<br><br>Alternatively, "the quantity of material covering the surface includes an amount of anti-abuse substance." |

C2R asserts that the term "layer" in claim 1 of the '837 Patent requires a solid characteristic. According to C2R, this is because the specification discloses the layer as solid, and contains no suggestion that the layer can be anything other than solid. C2R primarily relies on the depiction of the "layer" components of the invention in three figures included in the specification. Figure 1 depicts a "skin-worn patch **10**," which "includes a skin fastening adhesive-containing *layer* **12** and an opioid containing *layer* . . . **14**," as well as "a disposal container or pouch [**16**]" that "includes a *layer* of absorbent

material **18** attached to one side of the container **16**." '837 Patent col. 4, ll. 11–19 (emphasis added). Figures 2a and 2b depict a second embodiment including a patch having a drug material "such as an opioid contained in a *layer* **32**" and a "*layer* [**34**] containing an amount of absorbent material." *Id.* col. 4, ll. 33–37 (emphasis added). These layers (12, 14, 18, 32, and 34), says C2R, are depicted as having a solid characteristic:

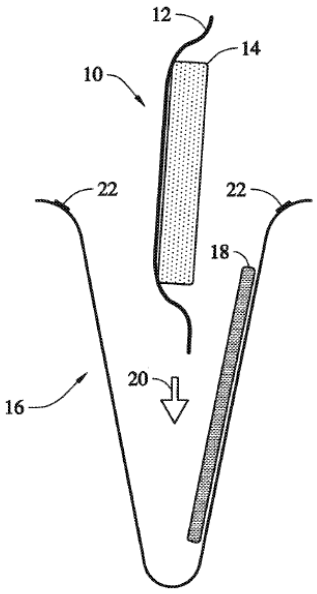



FIG. 1

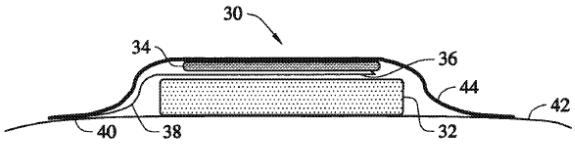



FIG. 2a

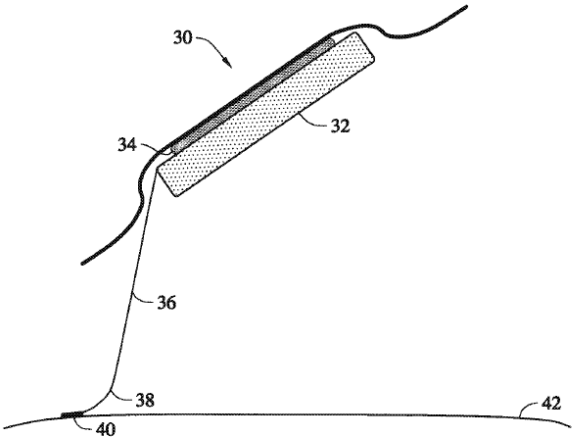



FIG. 2b

C2R also maintains that the purpose of the embodiment in Figure 1 is to allow a user to remove a patch and contact it directly to the deactivating material, and a liquid layer would render this embodiment unsuitable for its use. In addition, when referencing liquids, the specification uses the terms "solution" and "solvent," rather than "layer." *See* '837 Patent col. 3, ll. 18–27. Finally, C2R contrasts the '837 Patent to the '711 Patent, which is in the same patent family, noting that the '711 Patent discusses adding water to a pouch, and use of a gelling agent in a mixture of water and activated carbon to suspend the activated carbon in a liquid mixture, while nothing in the '837 Patent suggests incorporation of liquid in any way.

In response, Verde asserts that there is no support in the claims, specification or prosecution history to limit "layer" to solids. Verde points out that the '837 Patent specification never uses the word solid, let alone in reference to the "layer," in contrast with the '711 Patent, which specifically refers to a "solid" (film) layer as a potential form of a layer. *See* '711 Patent col. 2, ll. 49–57. Moreover, the descriptions in the patent specification of the layers as "containing" certain materials—e.g., an "opioid-*containing* layer 14"—suggest that the "layer" consists of dispersed molecules that may or may not be in the same physical state, which is consistent with the typical understanding of a POSA (citing Worthen Decl., ECF Doc. No. 138, at 23–40, ¶ 29).

Finally, Verde asserts that C2R's proposed construction increases ambiguity and invites the Court to commit a "cardinal sin" of claim construction by limiting the claims to the preferred embodiment in the specification and figures absent a clear demonstration that was the patentee's intent.

Contrary to C2R's assertions, the Court does not find any basis in the intrinsic record to conclude that the term layer includes only solids, and not other forms of matter. Nothing in the '837 Patent claims indicates that the plain and ordinary meaning of "layer" should be so limited. Claim 1 does not specify the physical characteristics of the "layer" at issue, other than to require that the layer "contain[] an amount of an anti-abuse substance comprising . . . activated carbon" and that the layer be "disposed in [the] container" so that the proper insertion of a transdermal patch into the container "will cause [the] abusable substance [in the patch] to contact" the layer. This language does not exclude the possibility of a liquid layer.

Nor does the specification provide any reason to construe the term layer to exclude non-solid forms of matter. C2R relies on the description of the first embodiment, in which the layer is "attached to one side of the container," and asserts that the layer therefore must be sufficiently solid, and not a liquid

dispersion, to be attached to one side of the container.[4] But this "attachment" feature is not a requirement of claim 1. In fact, by virtue of claim differentiation, claim 1 necessarily must be read to include devices in which the layer is *not* attached to one side of the container: claim 11—a dependent claim not alleged to be infringed—claims "[t]he device according to claim 1, wherein said layer containing an amount of an anti-abuse substance is attached to one side of said container." Reading claim 1 to require that the layer be attached to the side of the container would render the additional limitation of claim 11 superfluous. *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380–81 (Fed. Cir. 2006).

C2R's reliance on the two embodiments and corresponding figures in the specification—which C2R asserts "contain[] no suggestion that the layer can be anything other than solid"—also is misplaced. C2R focuses on only two possible embodiments of the invention, and what those embodiments "suggest" the patent may cover, rather than on what the specification clearly and manifestly *excludes*. In doing so, C2R improperly limits the subject matter of the patent to the preferred embodiment and the configuration set forth in the drawings. *See, e.g.*, *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) ("[D]rawings in a patent need not illustrate the full scope of the invention. . . . Moreover, 'even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction.'"); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) ("[P]atent coverage is not necessarily limited to inventions that look like the ones in the figures. . . . To hold otherwise would be to import limitations onto the claim from the

[4] In reference to the second embodiment described in the specification, C2R asserts, without supporting evidence, that "a liquid dispersion containing activated carbon could not be worn in a skin-worn patch." At the claim construction hearing, Verde's counsel asserted, also without supporting evidence, that transdermal patches such as the one described in the specification and figures can have a liquid layer. The Court will not rely on either of these unsubstantiated statements in construing the meaning of the term layer in claim 1 of the '837 Patent.

specification, which is fraught with 'danger.'"); *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1342 (Fed. Cir. 2001) ("These drawings are not meant to represent 'the' invention or to limit the scope of coverage defined by the words used in the claims themselves."). C2R points to no such manifest restriction requiring this limitation.

That the specification uses the words "solvent" and "solution" to refer to water, ethanol, and a liquid mixture containing fentanyl citrate likewise does not express an intent to exclude liquid layers from patent coverage. C2R's implication is that the inventors of the '837 Patent should have used a word such as solvent or solution if they wanted the patent to cover liquids, and by not doing so, they necessarily chose to exclude liquids. This argument, if it is indeed C2R's position, presents a false dichotomy. The word "layer" is broad enough to cover both liquids *and* solids. If the inventors intended their invention to cover both forms of matter—which the Court concludes they did—then use of a narrow term that applies to *only* solids or *only* liquids would make little sense. The inventors chose a more general word, and are entitled to the benefit of the "full range" of its ordinary meaning.

Although the Court's decision is based solely on the intrinsic evidence, the extrinsic evidence provides further support for construing layer to include non-solid matter. Dictionary definitions are uniform in defining a layer as a quantity or thickness of material, without regard to state of matter. *See* THE AMERICAN HERITAGE DICTIONARY (4th ed. 2000) (defining layer as "[a] single thickness of a material covering a surface or forming an overlaying part or segment" and "[a] usually horizontal deposit or expanse; a stratum," with an example of the latter including "a layer of warm air"); NEW OXFORD AMERICAN DICTIONARY (3rd ed. 2010) (defining layer as "a sheet, quantity, or thickness of material, typically one of several, covering a surface or body"); MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2003) (defining layer as "[o]ne thickness, course, or fold laid or lying over or under another"). C2R's construction, "a solid thickness of material," improperly inserts the word "solid," which is not found in any of the dictionary definitions above. Verde's

construction, on the other hand—a "quantity of material covering a surface"—more accurately encompasses the various dictionary definitions of layer.[5]

In sum, the Court declines to read a "solid" limitation into the word layer, because the meaning of the term is clear in view of the language of the claims and specification. The Court adopts Verde's construction of the word layer as a "quantity of material covering a surface."

**2. "Seal" terms ('711 Patent claims 1, 7, and 11)**

The parties have proposed the following constructions of these disputed claim terms:

| Claim Term | Term Location | C2R's Proposed Construction | Verde's Proposed Construction |
|---|---|---|---|
| "sealable" | '711 Patent Claim 1 | "capable of being impervious to organic vapors" | *No further construction necessary.*<br><br>Alternatively, "capable of being shut or closed"<br><br>Alternatively, and given the claim language states "closure for sealing *container to thereby capture treated medication*," Verde proposes "closure for securing treated medication in the container." |
| "sealing" | '711 Patent Claim 1 | "making impervious to organic vapors" | *Verde construed this term as part of "closure for sealing" identified below.* |
| "resealable" | '711 Patent Claims 7 and 11 | "capable of being impervious to organic vapors again after being opened" | *No further construction necessary.*<br><br>Alternatively, "capable of being closed after opening" |

[5] C2R's expert did not offer an opinion on the meaning of the word layer. Verde's expert did not expressly opine on whether the term layer includes liquids, but asserted that layer, as understood by a POSA, was not limited to solids. *See* Worthen Decl. ¶ 28 ("The specification uses the term throughout as a non-specific composition of material without regard to the physical state of the material (whether it be solid , liquid, gelatinous, aqueous or dispersed). This is consistent with the understanding of a POSA that a 'layer' is not strictly limited to something that is solid, in sheet form, or monolithic."); *id.* ¶ 29 (the specification suggests "that the 'layer' consists of dispersed molecules that may or may not be in the same physical state").

C2R argues that the proper construction of "sealable," "sealing," and "resealable" requires a barrier to vapors or gases. C2R cites the following portions of the '711 Patent specification in support of its construction:

- The description of Figure 1 as depicting a drug disposal pouch "having an outer barrier substantially impervious to water and organic vapor with active binding agents incorporated within." '711 Patent col. 5, ll. 35–39.
- The summary of the invention noting that activated carbon "has a finite capacity for adsorption," and asserting: "If the activated carbon is exposed to normal atmosphere in shelf storage, it will eventually become deactivated due to adsorption of gaseous impurities found in air. Therefore, it has been found that activated carbon used in accordance with this invention requires protection from deactivation by contamination during storage conditions to preserve and prolong shelf life." '711 Patent col. 3, ll. 49–57.
- The summary of the invention, describing a "further aspect of the invention" in which the containers "are sealed while in storage prior to use and are kept substantially impermeable to gaseous organic compounds so that the activated carbon retains its adsorption capability." '711 Patent col. 4, ll. 32–34.

According to C2R, construing the term "seal" to permit gas flow would defeat the purpose of the seal and fail to protect the carbon. In addition, C2R contends that the only examples of seals in the specification—Ziploc and adhesive seals—are impervious to vapors. C2R adds that dictionary definitions confirm its position that a "seal" must prevent gas flow.

Finally, C2R asserts that "seal" cannot mean "close," as Verde proposes, because the two words have different meanings; Verde chose to use the narrower term "seal," rather than the broader term "close," as it did in the '837 Patent. According to C2R, "[b]y using the word seal as opposed to close, the patentee claimed the specific qualities of a seal, which prevent gas from penetrating the barrier."

In response, Verde asserts that the claims and the specification make clear that the "seal" required by the patent need only be sufficient to keep the

medication and anti-abuse substance *within* the container—not to keep air and gas out. For example:

- Claim 1 discloses a container "including a closure for sealing said container to thereby capture a treated medication." Per Verde, this claim language makes clear that the purpose of the "sealing," is to contain the treated medication, not gases or vapors.
- Claim 6, and its dependent claim 7, separately claim "[a] disposal system as in claim 1 wherein said container is impervious to organic vapors." C2R's proposed construction, which would read imperviousness into the "seal" of independent claim 1, is precluded by the doctrine of claim differentiation.[6]

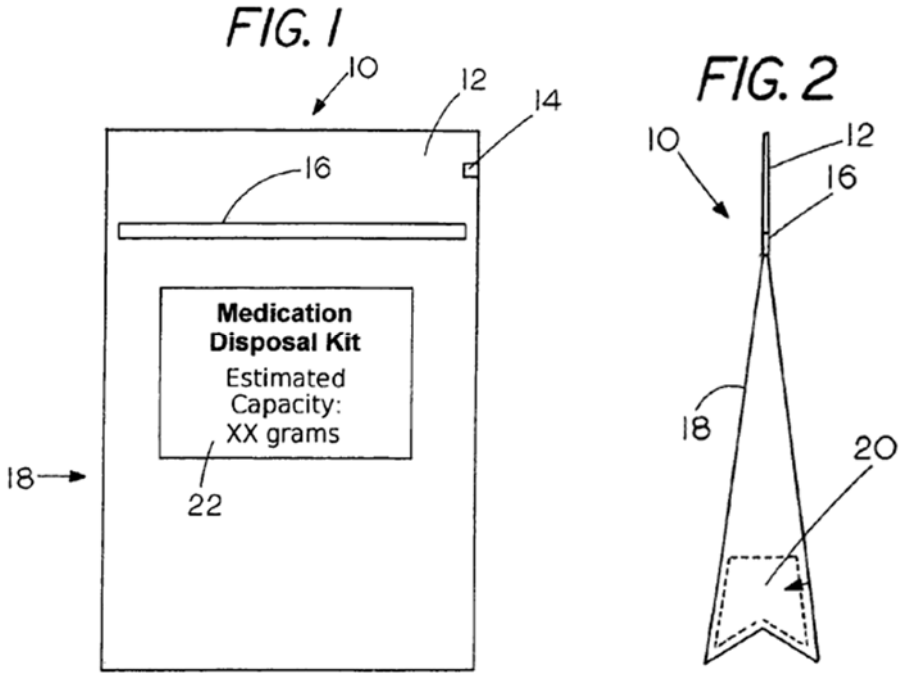
Turning to expert testimony, Verde claims that POSAs generally recognize that "seal" does not necessarily connote a closure that is airtight or gas-impervious, and therefore typically use phrases such as "hermetic" or "impervious" to indicate an airtight seal (citing Worthen Decl. ¶¶49-51), and that even C2R's expert Dr. Sand admitted that not all "adhesive" or "Ziploc" style closures are airtight thus not even the preferred embodiments necessarily include seals that are "impervious to organic vapors."

Finally, Verde asserts that, when the patent specification discusses imperviousness to organic vapors, the concern is vapors getting into the package during storage, not being vented after "sealing." Moreover, gas—and vapor—resistance is not a requirement for product function, just preferred to optimize the shelf life of the product.

The intrinsic evidence supports Verde's construction of this claim term. C2R's reading, in contrast, improperly limits the purpose of the seal to one function (protecting the carbon) and also conflates the sealed "outer barrier" of the container with the seal meant to contain the treated, deactivated drug. The specification's summary of the invention describes these two different concepts: "In a further aspect of the invention, the disposable containers are sealed while in storage prior to use and are kept substantially impermeable to gaseous

[6] In reply, C2R asserts that the doctrine of claim differentiation does not apply in the way Verde suggests, because claim 6 applies to the *container*, not the seal.

organic compounds so that the activated carbon retains its adsorption capability." '711 Patent col. 4, ll. 31–34. This "further aspect" of the invention is demonstrated in the embodiment shown in Figures 1 and 2:




The specification describes Figures 1 and 2 as

> depicting a medication disposal kit . . . in the form of a disposal pouch having an outer barrier substantially impervious to water and organic vapor with active binding agents incorporated within. The pouch is depicted generally by **10** and includes a seal layer **12** that can be opened using a tear notch **14** . . . [as well as] a reusable zip lock seal **16** so it can be reclosed after insertion of the waste medications. The pouch has an outer barrier **18** that is of a material substantially impermeable to organic vapors such as aluminum foil.

'711 Patent col. 5, ll. 36–27.

The specification's concern for outer package integrity, on which C2R focuses, relates *not* to the closure seal at issue in the disputed claims (which is labeled with the number 16 in the embodiment depicted in Figures 1 and 2), but instead to the "outer barrier" (depicted as number 18) and its seal (number 12). *See also id.* col. 6, ll. 20–27 (referring to the step of opening an

"impermeable seal" to expose the kit contents, and then resealing the pouch after medication is added). The purpose of the "seal" function described in claims 1, 7, and 11 of the '711 Patent is to prevent the escape of the abusable substance—to prevent *exit* rather than *entry*.

Principles of claim differentiation also undercut C2R's argument.[7] Claim 6 of the '711 Patent adds a limitation that the container be impervious to organic vapors, which means that claim 1 necessarily includes containers that are *not* impervious to organic vapors. C2R asserts, after pointing out that one purpose of the invention is to protect the activated carbon from deactivation during storage: "It would make little sense to attempt to optimize shelf life using an impervious container with a seal that permits air to enter the container." But, if claim 1 covers containers that are not airtight, it would make little sense to construe that claim to require that the container have a seal that is impervious to vapors; adding an airtight seal on a nonairtight container does little to optimize shelf life.

In short, it is primarily the outer packaging, and (recommended) pre-use storage conditions that keep gaseous vapors *out* so that the activated carbon or other anti-abuse substance does not become deactivated prematurely. It is the primary function of the "closure" seal to keep the activated carbon, and the abusable substance (and water or gel) *in*, so that the abusable substance becomes deactivated and the whole mixture can be disposed of. C2R's proposed construction improperly imports the limitation that the closure seal be airtight, and therefore the Court must reject this construction. The Court instead adopts Verde's proposed construction of the disputed terms, which afford them their plain meaning.

[7] These overall distinctions between outer packaging and closure seal hold, even accepting claim differentiation as "a guide, not a rigid rule" in this instance. *Curtiss-Wright Flow Control*, 438 F.3d at 1381 (internal quotation marks omitted) (quoting *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991)).

### 3. "Closure" terms ('837 Patent claim 1 and '711 Patent claim 1)

The parties have proposed the following constructions of the disputed claim terms:

| Claim Term | Term Location | C2R's Proposed Construction | Verde's Proposed Construction |
|---|---|---|---|
| "closure means for closing" | '837 Patent Claim 1 | Governed by 35 U.S.C. § 112 ¶ 6 | *No further construction necessary.*<br><br>Alternatively, a "closure device." |
| "closure for sealing" | '711 Patent Claim 1 | Governed by 35 U.S.C. § 112 ¶ 6 | *No further construction necessary.*<br><br>Alternatively, and given the claim language states "closure for sealing *container to thereby capture treated medication,*" Verde proposed "closure for securing treated medication in the container." |

C2R asserts that both "means for closing" and "closure for sealing" are drafted to invoke means-plus-function treatment. In the '837 Patent, the use of the word "means" creates a rebuttable presumption that the term is intended to be a means-plus-function claim. C2R contends that the presumption is not overcome, because the claim does not explicitly disclose the structure needed to perform this function (the term "closure" itself does not provide sufficiently definite structure).

As for the '711 Patent, even though "closure for sealing" does not use the word "means," C2R argues that this is a means-plus-function term because it lacks sufficient structure and merely recites a function ("sealing said container"). Because the term "closure" as understood by persons of ordinary skill in the art does not provide a sufficiently definite meaning as the name for structure, the term is drafted as a means-plus-function term.

In response, Verde argues that the claims are not means-plus-function claims because "closure" is understood by POSAs to connote structure. While the word "closure" may cover a broad class of structures, it is commonly understood by POSAs to identify actual structure (citing Worthen Decl. ¶¶36,

40-45). In addition, the specifications of both the '837 Patent and the '711 Patent use the word "closure" in reference to structural elements. Because a POSA would understand "closure" to be the structural name for "something that closes or shuts," § 112 ¶ 6 does not apply.

The initial dispute between the parties about this category of terms is whether the Court should apply the "means plus function" test of 35 U.S.C. § 112(f). If the Court would apply that test, it would mean, ultimately, that one or both patents have lesser exclusionary force toward potential infringers, as the claim term would be limited to cover only the structure or material described in the specification (and equivalents thereof) that perform the function of closing. To refresh, where a patent includes the word "means" then the Court may presume that the inventor used that word to invoke the statutory mandates for the means-plus-function clause. *Sage Prod.*, 126 F.3d at 1427–28. But, that presumption may be overcome.

Here, the '837 Patent uses the word 'means' in "a closure means for closing" in claim 1. Specifically: "A device comprising: . . . (c) a closure means for closing said container containing a used skin-worn patch device." Claim 1 does not prescribe the particular structure of the closing means. Yet dependent claim 7 states: "The device according to claim 1, wherein said closure device includes an adhesive seal." And dependent claim 10 states: "The device according to claim 1, wherein said closure means comprises a zip lock seal."

The specification of the '837 Patent describes a feature of one form of the system as follows: "A closure device for closing the container or pouch is also provided so that the container can also provide a closed system for disposing of the used skin-worn patch. The closure system may include an adhesive seal or zip lock to seal the patch in the container." '837 Patent col, 2 ll. 61–65. The Court also notes that the specification includes the following disclaimer: "This invention has been described herein in considerable detail . . . [but] it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the

equipment and operating procedures, can be accomplished without departing from the scope of the invention itself." *Id.* col. 5, ll 32–43.

Verde has tried to overcome the presumption that the means-plus-function test should apply, despite the '837 Patent's use of the word "means," by citing to United States Pharmacopeia ("USP") definitions for packaging human drugs and biologics. Verde's expert, Dr. Worthen, pointed to definitions of the terms 'packaging system', 'container', 'closure' and 'packaging component'. "Closure" is defined by USP as "[a] material that seals an otherwise open space of a Container and provides protection for the contents. It also provides access to the contents of the Container (e.g. screw caps and stoppers)." Worthen Decl. ¶ 38. Thus, according to Dr. Worthen, the term "closure" is used commonly and by POSAs to designate the particular structural element that actually closes a container, and was the case at the time the '837 Patent was filed.

C2R has elicited the opinion of Dr. Claire Koelsch Sand, to counter that of Dr. Worthen. Dr. Sand's opinion is that the term "closure means for closing" recites only a function, and does not sufficiently recite a structure. She does not read claim 1(c) to include a specific closure mechanism that would seal and allow reclosure of its broad definition of containers. In her opinion, in the packaging industry, a POSA would not consider a Ziploc-type feature to be a "closure." In the packaging industry, "closure" is commonly restricted to apply to rigid closures, and not flexible structures. She considers both patents at issue to use the term "closure" in the lay sense. "Closure," therefore, cannot be read to identify a specific structure but simply a function. *See* Sand Decl. (ECF Doc. No. 122) ¶¶ 31–37.

As noted earlier, Verde moved to strike the testimony of Dr. Sand as not relevant. Admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, (1993); *Burton v. Am. Cyanamid*, 362 F. Supp. 3d 588, 596 (E.D. Wis. 2019). When a witness is qualified as an expert by knowledge, skill, experience, training or education and seeks to testify in the form of an opinion or

otherwise, based on his or her scientific, technical or other specialized knowledge, in order to help the trier of fact to understand the evidence or determine a fact in issue, and when his or her testimony is based on sufficient facts or data, and is the product of reliable principles and methods, and where he or she has reliably applied those principles and methods to the facts of the case, then the court may accept that witness' testimony. Fed. R. Evid. 702. The inquiry here, where there is a dispute about which field or fields are relevant to the invention, is whether Dr. Sand has sufficient relevant technical experience to assist the Court. *See SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010), *overruled on different grounds by Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011) (allowing testimony where there was an adequate relationship between the expert's experience and the claimed invention, but not a broader related group); *Zipshade Indus. (B.V.I.) Corp. v. Lowes Home Ctrs., LLC*, No. 2:14-CV-05934-ODW (JC), 2017 WL 2766163, at *4 (C.D. Cal. June 26, 2017) (allowing testimony of mechanical engineer with expertise in claimed pulley systems as component of patented device but not on other aspects of window coverings).

Dr. Sand is an expert in packaging. She has a Bachelor of Science and a Master of Science in packaging and a Ph.D. in food science and nutrition. She opined that for the packaging devices disclosed in the '837 and '711 patents, a POSA "would have a design, packaging, or related degree and/or have 2 or more years of experience in the packaging industry." Sand Decl. ¶ 28. In contrast, Dr. Worthen has a Bachelor of Science in pharmacy, a Master of Science in toxicology and a Ph.D. in medicinal chemistry and pharmaceutics, as well as a law degree. His opinion is that, with regard to these two patents, a POSA "would have at least a Bachelor of Science degree in chemistry or pharmaceutical sciences and approximately 5-7 years of experience in pharmaceutical product development and the pharmaceutical industry." Worthen Decl. ¶ 16.

There can be more than one field of pertinent art. Pertinent art is the art or arts to which one can reasonably be expected to look to solve a problem

which the patented device attempts to solve. *Roberts v. Sears, Roebuck & Co.*, 773 F.2d 1324, 1334 (7th Cir. 1983); *see also Dickey-john Corp. v International Tapetronics Corp.*, 710 F.2d 329, 344 (7th Cir. 1983) (inventors can look to more than one pertinent art in attempting to solve the problem; district court found that both planter monitor art and general electronics art were pertinent to device that combined a photocell with a planter apparatus). Verde asserts that Dr. Sand is not a relevant expert because she has no experience designing packages that use activated carbon, designing packaging for pharmaceutical products, working with medical waste disposal, or with environmental disposal or contamination. Both the '837 and '711 patents address a system and method for reducing the potential for substance abuse and environmental contamination from unused and expired medications. While Verde's assertions about Dr. Sand's direct experience may be true, the "system and method," or "pertinent art" of the inventions at issue necessarily involves some sort of packaging or containment. Dr. Sand's testimony spoke to issues of packaging and she refrained from testimony involving any pharmacological or environmental aspects. The Court finds that Dr. Sand, as a packaging expert, has sufficient relevant technical evidence to assist the Court.

For the '837 Patent, Verde has not overcome the presumption that "a closure means for closing" is a means-plus-function term under section 112(f). Claim 1(c) does not go on to elaborate sufficient structure to perform entirely the recited function. In fact, it says virtually nothing about structure of the closure means. That several dependent claims (Nos. 10 and 12) identify particular possible options for closure means structure cannot substitute as sufficiently elaborated structure within claim 1(c) itself. *See, e.g., Air Turbine Tech., Inc. v. Atlas Copco AB*, 295 F. Supp. 2d 1327, 1332 (S.D. Fla. 2003) ("[D]ependent claims must be construed to include all limitations of the independent claims incorporated therein. Therefore, if the independent claims fail to contain sufficient structure to rebut the presumption that they are in means plus function format, the dependent claims cannot 'save' such claims from being means plus functions claims."); *Round Rock Research LLC v. Acer,*

*Inc.*, No. CV 11-1011-RGA, 2013 WL 12315522, at *1 (D. Del. June 21, 2013) ("This theory that dependent claims can provide enough structure for a term in an independent claim to overcome that presumption is not supported by any tenet of claim construction. 'The claim itself' must recite the structure to overcome the presumption.").

Verde offers Dr. Worthen's testimony, which includes the UPS definition of "closure." But that refers to a "material"—not an elaboration of sufficient structure to perform entirely the recited function. Dr. Worthen opined that "while the word 'closure' may cover a broad class of structures, it is commonly understood by POSAs to identify an actual structure." The Court agrees with the first part of Dr. Worthen's statement, and finds that while the second part generally may be true, in a patent where the term "closure" knowingly is used by the inventor together with the term "means" with no further elaboration of the structure for the particular function, it must be regarded as a mean-plus-function term.

Dr. Sand's opinion seemed to blend in both claim 1(c) and the dependent claims 10 and 12 (regarding alternative closure means of Ziploc and adhesive) but those are not controlling in assessing the independent claim 1(c). *See, e.g., Air Turbine Tech.*, 295 F. Supp. 2d at 1332. Her testimony does dovetail with Dr. Worthen's in that the word "closure" may cover a broad class of structures, but she goes further to state that "closure devices are so commonplace that the existence of closure devices is often not mentioned or is implied," and that by mentioning "closure" a patent would guide the POSA "to understand [the closure's] function or role in the package but not identify the specific structure that performs the closing." Sand Decl. ¶ 36.

For the reasons stated, the Court adopts C2R's proposed construction of "closure means for closing" in claim 1 of the '837 Patent, and concludes that 35 U.S.C. § 112(f) applies. The "function" of the means is to close the container, and the structures described in the specification corresponding to this claimed function are (1) an adhesive seal/strips and (2) a "zip lock." *See* '837 Patent col. 2, ll. 61–65 and col. 4, l. 25.

For the ’711 Patent, which uses the phrase “closure for sealing,” the analysis is a bit different because the word “means” is not part of the claim term. Claim 1(c) provides that the container must include “a closure for sealing said container to thereby capture a treated medication.” Claim 1(c) is somewhat parallel to claim 1(a), which reads “a disposable, *sealable* container that can be opened to receive an amount of unused medication substance therein” (emphasis added). There was not that same parallelism in claim 1(a) of the ’837 Patent, which lacked any mention of closure or closable. While those two differences exist, and the two experts maintain their disparate views for the same reasons, the Court’s conclusion is the same. A “closure for sealing” is no more descriptive of structure than is a “closure means for closing.” POSAs either will have an almost limitless array of closure possibilities in mind (Worthen), or they will be at a loss (Sand). But that wide array identified by Worthen really means a function, and not a structure. Worthen’s argument would turn function into structure, much like nominalization turns verbs into nouns and passive voice ensues.

The Court adopts C2R’s claim construction of “closure for sealing” in claim 1 of the ’711 Patent, and concludes that 35 U.S.C. § 112(f) applies. The “function” of the means is to close the container after receiving the abusable substance, and the structures described in the specification corresponding to this claimed function are (1) an adhesive seal and (2) a zipping reusable seal, including “a plastic container reseal device such as those associated with the trademark Ziploc.” *See* ’711 Patent col. 4, ll. 49–55 and col. 5, ll. 42, 53.

**4. Preamble (’711 Patent claim 1)**

The parties have proposed the following constructions of the disputed claim term:

| Claim Term | Term Location | C2R’s Proposed Construction | Verde’s Proposed Construction |
|---|---|---|---|
| “A disposal system for reducing substance abuse or environmental contamination from unused medications, said system” | ’711 Patent Claim 1 | The preamble is not limiting | *No further construction necessary.* |

C2R asserts that the preamble to claim 1 of the '711 Patent does not have a limiting effect, because it recites only an intended use and fails to recite essential structure or form an antecedent basis for any limitation in the body of the claim. Additionally, Verde did not clearly rely on the preamble during patent prosecution to distinguish the prior art.

Verde, on the other hand, asserts that the preamble *is* limiting because Verde and the USPTO "clearly and unmistakably" relied on this language to distinguish the prior art and to "further define" the claimed invention.

In general, a preamble limits a claim if it "recites essential structure or steps," or if it is "necessary to give life, meaning and vitality" to the claim, while a preamble is *not* limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks omitted). The Federal Circuit has identified certain guideposts in analyzing whether a preamble is limiting:

- "Jepson" claiming (describing the prior art and then claiming an improvement over the prior art in the preamble) "generally indicates intent to use the preamble to define the claimed invention, thereby limiting claim scope."
- "[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention."
- "[W]hen the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope."
- "[W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation."
- "[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention."
- "Without such reliance, however, a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or

steps of the claimed invention. . . . Thus, preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant."

- "[P]reambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure."

*Catalina Mktg.*, 289 F.3d at 808–09.

Applying the *Catalina* factors, the preamble of claim 1 of the '711 Patent generally states the purpose of the invention, *i.e.*, "for reducing substance abuse or environmental contamination from unused medications." To this extent, the preamble does not limit the scope of the claim. Arguably, the first three words of the preamble, "[a] disposal system" and last two words, "said system" are more specific than just a purpose and could be said to define the claimed invention. But there can be many "systems" as well as myriad structures for "disposal systems." Here the preamble indicates the intended use of the device—disposal of unused medications—but does not provide any information about the claimed structure itself. *See Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010). Verde's assertion that the preamble language "further explains (to a POSA) the kind of container needed to practice the invention and limits the possible configurations" is off the mark, as the preamble adds no specificity to claim 1(a) which describes "a disposable, sealable container" and 1(b): " that prevents later independent extraction of said medication" and 1(c): "including a closure for sealing said container to thereby capture a treated medication." In short, deletion of the preamble of claim 1 of the '711 Patent would not affect its structure.

Verde also asserts that the USPTO and Verde relied upon the preamble language to distinguish prior art. C2R argues that the prosecution history focus was on the question of lack of adsorption and chemisorption agents, not on the preamble in distinguishing prior art. *See Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 F. App'x 941, 943 (Fed. Cir. 2014) (patentee clearly

relied on the preamble by arguing specifically that the claim was not obvious in light of the prior art, and thus allowable, because the prior art lacked the "selectively rotating" requirement disclosed in the preamble). Verde points to an excerpt from the USPTO Notice of Allowability, and italicizes the language of the preamble in that excerpt. *See* ECF Doc. No. 138, at 17. Yet the Notice itself not only recited the preamble but synthesized all three substantive segments of claim 1. There is no way a court, searching for the type of reliance identified by the Federal Circuit in cases like *Rotatable Techs.*, could separate the nonspecific preamble from the substantive segments of claim 1, all cited by the USPTO in its Notice of Allowability, to conclude that the patentees or the USPTO in fact distinguished prior art on the basis of the '711 Patent's preamble. The Court therefore finds in favor of C2R's proposed construction, that the preamble is not limiting.

**5. Intended use terms ('711 Patent claims 1 and 12, '837 Patent claims 1, 8, and 9)**

The parties have proposed the following constructions of the disputed claim terms:

| Claim Term | Term Location | C2R's Proposed Construction | Verde's Proposed Construction |
|---|---|---|---|
| "to receive an amount of unused medication substance therein" | '711 Patent Claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.*<br><br>Alternatively, and considering the claim language states: "a disposable, sealable container that can be opened to receive an amount of unused medication substance therein," Verde proposes "a disposable, sealable container that can be opened to allow insertion of an amount of unused medication substance therein." |

| | | | |
|---|---|---|---|
| "for treating said medication on contact" | '711 Patent Claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.*<br><br>Alternatively, and given the claim language states "an active binding agent in said container for treating said medication on contact," Verde proposes "an active binding agent that binds with the medication upon contact." |
| "such that insertion of said medication into said container will cause said medication to contact said binding agent" | '711 Patent Claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.*<br><br>Alternatively, "inserting the medication into the container causes the medication to contact the binding agent." |
| "to dissolve said unused medications that are in solid form" | '711 Patent Claim 12 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.* |
| "to receive a skin-worn patch device containing a residual amount of an abusable substance therein" | '837 Patent Claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.*<br><br>Alternatively, and considering the claim language states: "an independent disposable container having an opening therein to receive a skin-worn patch device containing a residual amount of an abusable substance," Verde proposes "an independent disposable container having an opening therein allowing insertion of a skin-worn patch device…" |
| "said layer being disposed in said container in a manner such that a skin-worn patch device properly inserted into said container will cause said abusable substance to contact said layer containing said anti-abuse substance" | '837 Patent Claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.*<br><br>Alternatively, "inserting the skin-worn patch into the container causes the abusable substance to contact the anti-abuse substance." |

| | | | |
|---|---|---|---|
| "containing a used skin-worn patch device" | '837 Patent Claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.*<br><br>Alternatively, and considering the claim language states: "a closure means for closing said container containing a used skin-worn patch device," Verde proposes "closure device that seals the used skin-worn patch inside the container." |
| "wherein said abusable substance is an opioid" | '837 Patent Claim 8 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.* |
| "wherein said abusable substance is fentanyl" | '837 Patent Claim 9 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use | *No further construction necessary.* |

C2R asserts that the above terms in the '837 Patent and the '711 Patent are "intended use terms" that carry no patentable weight. Because both patents recite apparatus claims—and therefore are limited by the claimed structures rather than the intended use or purpose of the devices—the disputed terms, which merely state an intended use or function of the devices, do not limit the claims. Instead, says C2R, the devices need only possess the capability of performing the recited functions.

In contrast, Verde contends that the phrases identified by C2R "further define and limit the claims of the inventions" and therefore have patentable weight. *See* ECF Doc. No. 138, at 20 ("The phrases . . . identify[] certain requirements that necessarily narrow and specify the structures that can be used to practice the invention. The phrases limit possible structure size, shape, impact, material, number, and more. The phrases also provide necessary context for surrounding claim language.").

The nub of the test for whether these "intended use" terms have patentable weight, is to consider the claim language without them. Would there then be a material impact on the claim scope? *See Matthews Int'l Corp. v.*

*Vandor Corp.*, 725 F. App'x 1002, 1003 (Fed. Cir. 2018). In particular, would the intended use term somehow limit or define or differentiate the structure? *Tabletop Media, LLC v. AMI Entm't Network, LLC*, No. 16-CV-1121-RGA-MPT, 2018 WL 2949467, at *6 (D. Del. June 13, 2018) ("A patent applicant is free to recite features of an apparatus either structurally or functionally, [but] the patentability of an apparatus depends on the claimed structure, not the use or purpose of that structure. . . . Thus, [t]o limit an apparatus claim, the functional language must result in a structural difference in the claimed apparatus. . . . Where the language does not structurally differentiate the claimed apparatus, such as language that states an intended use of the invention, the language is not limiting.") (internal quotation marks omitted) (quoting *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997); *Microsoft Corp. v. Commonwealth Sci. & Indus. Research Org.*, 572 F. Supp. 2d 786, 795 (E.D. Tex. 2008)).

Only two of the terms in the '711 Patent limit or affect structure, and only one of the intended use terms in the '837 Patent implicates structure. All three of these implicate structure because they require the abusable medication to come into contact with the anti-abuse substance inside the container. That is how the medication becomes neutralized and no longer abusable. Therefore the container must be constructed in such a manner that this contact necessarily will take place, whether the medication is in solid or liquid form and whether the anti-abuse substance layer is in solid or liquid form.

Accordingly, the claim terms "for treating said medication on contact"; "such that insertion of said medication into said container will cause said medication to contact said binding agent"; and "said layer being disposed in said container in a manner such that a skin-worn patch device properly inserted into said container will cause said abusable substance to contact said layer containing said anti-abuse substance" have patentable weight and need no further construction.

Conversely, the remaining intended use terms "to receive an amount of unused medication substance therein"; "to dissolve said unused medications that are in solid form"; "to receive a skin-worn patch device containing a residual amount of an abusable substance therein"; "containing a used skin-worn patch device"; "wherein said abusable substance is an opioid"; and "wherein said abusable substance is fentanyl" are intended use terms that carry no patentable weight so long as the structure is capable of performing the intended use.

**CONCLUSION AND ORDER**

For the foregoing reasons, the Court provides the following constructions of the disputed claim terms/phrases:

| **Disputed Term** | **Location** | **Construction** |
|---|---|---|
| "layer" | '837 Patent claim 1 | "*quantity of material covering a surface*" |
| "sealable" | '711 Patent claim 1 | "*capable of being shut or closed*" |
| "sealing" [container to thereby capture treated medication] | '711 Patent claim 1 | "*securing*" [treated medication in the container] |
| "resealable" | '711 Patent claims 7 and 11 | "*capable of being closed after opening*" |
| "closure means for closing" | '837 Patent claim 1 | Governed by 35 U.S.C. § 112(f) |
| "closure for sealing" | '711 Patent claim 1 | Governed by 35 U.S.C. § 112(f) |
| "A disposal system for reducing substance abuse or environmental contamination from unused medications, said system" | '711 Patent claim 1 (preamble) | The preamble is not limiting |
| "to receive an amount of unused medication substance therein" | '711 Patent claim 1 | Intended use limitation that carries no patentable weight so long as the structure is capable of performing the intended use |
| "for treating said medication on contact" | '711 Patent claim 1 | No further construction necessary |

| | | |
|---|---|---|
| "such that insertion of said medication into said container will cause said medication to contact said binding agent" | '711 Patent claim 1 | No further construction necessary |
| "to dissolve said unused medications that are in solid form" | '711 Patent claim 12 | Intended use limitation |
| "to receive a skin-worn patch device containing a residual amount of an abusable substance therein" | '837 Patent claim 1 | Intended use limitation |
| "said layer being disposed in said container in a manner such that a skin-worn patch device properly inserted into said container will cause said abusable substance to contact said layer containing said anti-abuse substance" | '837 Patent claim 1 | No further construction necessary |
| "containing a used skin-worn patch device" | '837 Patent claim 1 | Intended use limitation |
| "wherein said abusable substance is an opioid" | '837 Patent claim 8 | Intended use limitation |
| "wherein said abusable substance is fentanyl" | '837 Patent claim 9 | Intended use limitation |

**It is so ORDERED.**

Dated: February 20, 2020

By the Court:

Beth E. Hanan
United States Bankruptcy Judge